

REMARKS

Previously pending claims 2, 15, 17, 19, 21, 23, and 27 are canceled without prejudice or disclaimer.

New Claims 28 to 37 are presented. These claims are directed to a method of treating hepatic fibrosis. Support is found, e.g., at page 3, lines 15-28 and page 10, lines 25-26. It is submitted that these claims are patentable in all respects over the art applied in the Official Action of March 26, 2010; the rejections thereof are discussed hereinbelow:

35 U.S.C. §102(b)

Previous method Claims 2, 15, 17, 19 and 21 were rejected for lack of novelty. The art cited is Batkai et al. (Nature Medicine, vol. 7, no. 7 2001, pp. 827-832). The allegation is premised on Batkai et al.'s discussion of compound SR141716A and cirrhotic rodents. Without acquiescing to the propriety of this rejection, the new claims are directed to methods of treating hepatic fibrosis. Hepatic fibrosis is differentiate from cirrhosis and its treatment is patentably distinct.

This difference is well appreciated by the artisan. It is emphasized in this regard that cirrhosis, as alleged in Batkai et al., does not necessarily or inherently result in hepatic fibrosis, the treatment for which is claimed. Conversely, hepatic fibrosis is not necessarily or inherently caused by cirrhosis. The two illnesses are not identical.

For example, it is known that hepatic fibrosis is an early stage of many forms of liver injury, the treatment of which is contemplated by the instant claims. Batkai et al. on the other hand indicates that antagonists of the CB1 receptor may be used for decreasing the elevated mesenteric blood flow and portal pressure observed in cirrhosis, which is an end stage of many forms of liver injury. In other words, art such as Batkai et al. teach that CB1 receptor antagonists may reduce the vasodilated state in cirrhosis. In contrast, the present invention employs a CB1 receptor antagonist to treat hepatic fibrosis, targeting a different patient population to treat a different spectrum of pathologies to different effect than Bataki et al. The instant claims, which are specific to fibrosis, are thus novel over Batkai et al. Withdrawal of the rejection under 35 U.S.C. §102 is requested.

35 U.S.C. §103

Previously pending Claims 23 and 27 were rejected as obvious given Batkai et al. and US Patent No. 5,492,891 to Shakkebaek et al. The secondary reference was cited to provide an alleged nexus from alcoholic abuse and liver cirrhosis.

The present claims are not presaged by either of these references, be they taken alone or together. Batkai et al. is discussed above. It does not mention hepatic fibrosis or implicate it. This is because hepatic fibrosis is different from cirrhosis for the multiplicity of reasons given hereinabove. Shakkebaek et al. does not ameliorate this critical deficiency. No suggestion to treat hepatic fibrosis with antagonists of the CB1 receptor are derivable from the cited art.

Withdrawal of the rejection under 35 U.S.C. §103 is requested.

Wherefore, it is earnestly believed the instant application is in condition for allowance, passage to which is earnestly solicited.

Should the Examiner have any questions or wish to discuss any of the above or this case otherwise, they are invited to contact the undersigned as indicated.

Respectfully submitted,

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